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EXAMINER

HURT, SHARON L

ART UNIT PAPER NUMBER

1648

MAIL DATE DELIVERY MODE

10/29/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/620,787

Applicant(s)

SIMARD ET AL.

Examiner

Sharon Hurt

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-17 and 20-31 is/are pending in the application.
- 4a) Of the above claim(s) 3-6 and 12-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 7-10, 20-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The amendments to the claims filed August 9, 2007 have been acknowledged and entered. Claims 1, 8, 10, 20, 23 and 27-29 are currently amended. New claims 30 and 31 have been added.

Status of the Claims

Claims 1-10, 12-17 and 20-29 and new claims 30-31 are pending. Claims 11 and 18-19 have been canceled. Claims 3-6 and 12-17 have been withdrawn from consideration. Claims 1-2, 7-10, 20-29 and new claims 30-31 are under examination.

Response to Arguments

The rejection of claims 27-28 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement **is withdrawn**. Applicant's arguments, filed August 9, 2007 have been fully considered and are persuasive.

The rejection of claim 10 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement **is withdrawn** pursuant Applicant's amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 1-2, 7-11 and 20 under 35 U.S.C. 103(a) as being unpatentable over Hooper et al. in view of Thomson et al. is maintained for claims 1-2, 7-10 and 20.

Applicant's arguments filed August 9, 2007 have been fully considered but they are not persuasive. Applicant argues "Hooper does not teach or suggest the claimed polyproteins or immunogenic compositions comprised of such polyproteins." Applicant also argues "Hooper does not disclose polyproteins containing external immunogens of at least two membrane associated proteins of variola major." Hooper teaches L1R is a protein associated with the membrane and is thought to play a role in attachment or penetration (page 1, paragraph 007). Hooper teaches A33R is incorporated into the outer membrane (page 1, paragraph 007). Hooper also teaches L1R and A33R can be used as immunogens to produce monoclonal antibodies (page 2, paragraph 009). Therefore Hooper teaches immunogens of at least two membrane-associated proteins in poxviruses including variola virus (page 2, paragraph 009).

Applicant argues "Thomson does not teach or suggest polyproteins, particularly polyproteins comprising external immunogens of at least two membrane associated proteins wherein each of the external immunogens comprise a portion of the membrane-associated protein comprising the external epitopes." Thomson teaches a polyepitope protein which is a polyprotein, and the ability to deliver these in recombinant vaccinia virus (Abstract). Applicant also argues "that Hooper and Thomson are non-analogous art because Thomson teaches active immunization for CTL, not for antibodies." Hooper teaches monoclonal antibodies against vaccinia antigens L1R and A33R (membrane-associated proteins) protect against vaccinia infection (paragraph 009).

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It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to have consolidated the membrane proteins taught by Hooper into a single polyprotein, as taught by Thomson, as an effective method of delivering multiple antigens of variola major or vaccinia virus for the purpose of eliciting an immune response.

The rejection of claim 21 under 35 U.S.C. 103(a) as being unpatentable over Hooper et al. in view of Thomson et al. as applied to claims 1-2, 7-11 and 20 above, and further in view of Curiel et al **is maintained.**

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues that claim 21 depends from claim 20 and thus incorporated all the elements of claim 20. The rejection is applied to claim 21 as well as claims 1-2, 7-11 and 20 above. Therefore it incorporated the limitations of claim 20. The arguments over Hooper and Thomson have been discussed above.

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to use a biotin-streptavidin bridge to make a conjugate proteins from variola major and/or vaccinia because Curiel et al teach a high transfection efficiency when proteins are conjugated via biotin-avidin.

The rejection of claim 22 under 35 U.S.C. 103(a) as being unpatentable over Hooper et al. in view of Thomson et al. as applied to claims 1-2, 7-11 and 20 above, and further in view of Rutter et al **is maintained.**

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues that claim 22 depends from claim 20 and thus incorporated all the elements of claim 20. The rejection is applied to claim 22 as well as claims 1-2, 7-11 and 20 above. Therefore it incorporated the limitations of claim 20. The arguments over Hooper and Thomson have been discussed above.

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to anchor the proteins as taught by Hooper and Thomson in a liposome as taught by Rutter to facilitate delivery of the proteins.

The rejection of claims 23-29 under 35 U.S.C. 103(a) as being unpatentable over Hooper et al. in view of Thomson et al. as applied to claims 1-2, 7-11 and 20 above, and further in view of Newton et al is maintained for claims 23-29 and new claims 30-31.

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues "The combination of Hooper, Thomson and Newton does not teach or suggest all the elements of independent claims 23 and 29, specifically a polyprotein comprising external immunogens of at least two membrane-associated proteins of variola major or immunologically cross-reactive pox-viruses wherein the individual proteins are joined through a linker-spacer peptide and wherein each of the external immunogens comprises a portion of the membrane-associated proteins comprising the external epitopes." Hooper and Thomson in combination teach immunogenic compositions comprising polyproteins comprising membrane-associated proteins. Newton teaches flexible peptide linkers such as (GGGGS)₃ (Abstract). The combination of reference teaches the limitations of the instant claimed invention.

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New claim 31 is drawn to polyprotein LAA, as illustrated in Figure 9. Newton teaches the linker and Hooper teaches vaccine antigens. It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to use a flexible peptide linker as taught by Newton for joining peptide together and to use the poly-histidine tag taught by Newton to facilitate purification of the polyproteins.

Conclusion

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Hurt whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt

October 24, 2007

/Bruce Campell/
Supervisory Patent Examiner
Art Units 1645 (acting) and 1648